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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

18N2/1031

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CAMPELL, B

ART UNIT	PAPER NUMBER
1819	11

DATE MAILED: 10/31/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

for restriction purposes only

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ___ month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-77 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-77 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

BRINKS HOFER
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EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)
4/0,539

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1819.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-13 and 15-21, drawn to methods of making a chimeric ungulate, and methods of making ungulate embryonic stem (ES) cell cultures, classified in Class 435, subclass 172.3.

II. Claims 14, 22, 26-32, 39-56, 66-70, 75 and 77, drawn to chimeric ungulates and embryos, classified in Class 800, subclass 2.

III. Claims 23-25 and 76, drawn to methods of making transgenic ungulates by nuclear transfer, classified in Class 435, subclass 172.3.

IV. Claims 33 and 34, drawn to methods of making transgenic ungulates for use as xenograft donors, classified in Class 435, subclass 172.3.

V. Claims 35-38, drawn to methods of producing an exogenous protein in a transgenic ungulate, classified in Class 435, subclass 172.3.

VI. Claims 57-65, drawn to cell lines derived from ES cells of any species, classified in Class 435, subclass 240.2.

VII. Claims 71-75, drawn to ungulate embryos produced by nuclear transfer, classified in Class 800, subclass 2.

Claim 75 includes two distinct inventions. Should either of groups II or VII be elected, claim 75 will be examined to the extent that it encompasses the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the chimeric animals and embryos can be made by microinjection of DNA into cell nuclei. Furthermore, the compositions of II encompass millions of potential animals and ES cell lines, while the methods of I are variations of one method. Searching the prior art for II would require much additional searching not required for examination of I.

Group I is distinct from each of groups III and VII because the methods of I do not require nuclear transfer, while the method and product of III and VII do. Because of this additional procedure, the two methods are not obvious variants. Furthermore, different searches would be required for the two methods. Thus the inventions are deemed patentably distinct.

Group I is distinct from each of IV and V because IV and V contain limitations which require additional searches not required for examination of I. Group IV requires search of the xenograft and immunology arts, while V requires search of the "molecular farming" art. Neither IV nor V is an obvious variant of the generic methods for producing transgenic animals claimed in I. Therefore the inventions are deemed patentably distinct.

Groups I and II are each patentably distinct from group VI because the methods of I are limited to ungulates, while the ES cell lines of VI are not so limited. Thus considerable additional search (rodents, birds, etc.) would be required for VI which would not be required for examination of I or II.

Groups II and III are distinct because the method of III is not required to make the animals or stem cells of II. While the ES cells of II apparently could be used in the method of III, they can also be used in the methods of I. Different searches are required for the two inventions and there is nothing on the record to indicate that they are obvious variants. Therefore they are deemed patentably distinct.

Group II is distinct from each of groups IV and V because the compositions of II encompass millions of potential animals and ES cell lines, while the methods of IV and V are each variations of one method. Searching the prior art for II would require much additional searching not required for examination of I. Furthermore, transgenic ungulates can be made by other methods, such as microinjection.

Groups II and VII are distinct because they are drawn to materially different compositions, neither of which would render the other obvious. The embryos of VII result from mixing the nuclear genome of one donor with the mitochondrial genome and existing cytoplasmic RNAs and proteins of another donor. This is substantially different from mixing cell types in an embryo to make a chimera, as the embryos and animals of II are made. Different searches would also be required for the two inventions.

Groups III and VII are each distinct from each of groups IV and V because the compositions and methods of III and VII require nuclear transfer, while the methods of IV and V do not. Thus the two methods are materially different, require different searches, and are not obvious variants. Therefore the two pairs of inventions are deemed patentably distinct.

Groups III and VII are distinct because the compositions of VII encompass millions of potential animals and ES cell lines, while the methods of III are variations of one method. Therefore searching the prior art for VII would require much additional searching not required for examination of

III. Thus the two inventions are not obvious variants and are deemed patentably distinct.

Groups IV and V are distinct because they use different starting materials and procedures to achieve divergent ends. The two inventions require different searches and are not obvious variants, since success with one method would not be predictive of success with the other. Therefore the two inventions are deemed patentably distinct.

Group VI is distinct from each of III-V and VII because the methods and compositions of III-V and VII are limited to ungulates, while the ES cell lines of VI are not so limited. Thus considerable additional search (rodents, birds, etc.) would be required for VI which would not be required for examination of III-V and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached on 703-308-2035. The FAX phone number for art unit 1819 is 703-308-0294.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell
October 29, 1996

BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800